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Commentary Regulations Overburden Health Care

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A key goal of health care reform-providing health insurance for millions of uninsured Americans-demands greater scrutiny of the money we're currently wasting on health care regulation. Recent data suggest that 47-60 million Americans are without health insurance. Many people avoid seeking health care because it is too costly, and many who do seek care become burdened by high costs.

The total cost of health care regulation exceeds $339 billion, according to an Oct. 4, 2004, article in **Policy Analysis**, a publication of the **Cato Institute.** That figure takes into account regulation of health care facilities, health care professionals, health insurance, drugs and medical devices, and the medical tort system, as well as the costs of defensive medicine. The article estimates that the benefit of health services regulation exceeds $170 billion, leaving a net burden of $169 billion.

I don't mind having health care regulations if they provide a benefit to society or more efficient practice. What I can't stand is wasting more than $169 billion annually on health care regulations that serve no purpose. We are expected to practice evidence-based medicine, and we need to insist that the federal government practice evidence-based regulation.

In a 2002 report, "Care Without Coverage," the Institute of Medicine estimated that 18,000 uninsured Americans die each year because of a lack of health insurance coverage. Based on the median estimate of four studies cited in the Policy Analysis article, an additional 22,000 people die every year due to reduced societal income related to health care regulations. Clearly, there is an unappreciated human cost related to health care regulations.

To reduce or eliminate excessive regulatory costs, we can start by devising a simplified set of core regulations that are supported by good evidence of benefit. We need to consider scrapping all regulations that have a negative cost/benefit ratio, and regulations for which there is no evidence-based rationale. The emphasis cannot be simply on reducing costs; it needs to be based on factual evidence and improved quality of health care.

One way to achieve this is to overhaul the Food and Drug Administration, an agency that is overly restrictive, slow in making decisions, and hamstrung with isolation, hesitation, and fear of bad results. Many aspects of drug safety could instead be certified and ensured by independent, private-sector, voluntary institutions and by the tort system.

An overhauled FDA should provide a system of transparent peer review in the decision-making process regarding drugs and devices submitted. Data submitted to the FDA by drug and device companies should be made immediately available upon clearance of any product. Those companies also should be required to provide serious, concise, and truthful postmarket reporting.

As health care reform continues, we must empower physicians to do what they do best: Take care of people with real problems and train each other in best practices. Our current health care system is suffering because it is all about money, and not about people.